

REMARKS

Upon entry of the present reply, recited therein, and claims 1, 3-16 and 20-31 will remain pending.

Reconsideration of the rejections and allowance of the application in view of the following remarks are respectfully requested.

Statement of August 27, 2009 telephone interview

Applicants express appreciation for the courtesies extended by Examiners Walter Webb and Darryl Sutton during an August 27, 2009 telephone interview with Applicant's representative Arnold Turk.

During the interview, Applicants' claimed subject matter and specification including the disclosed examples were discussed accompanied by arguments that the rejections of record were without sufficient basis and should be withdrawn. In particular, Applicant's representative submitted arguments as set forth in Applicant's previous responses, including the previously set forth unexpected results set forth in Applicant's originally filed application. Moreover, it was indicated that the disclosure of Rajaiah is directed to the use of a lower viscosity polybutene as compared to the prior art disclosed therein, and that the weight percent of polybutene disclosed in Rajaiah appeared to be with respect to the polybutene component as compared to the composition, as seen in the Table on page 10 of Rajaiah with respect to Examples 1-37. Applicant's representative argued that one having ordinary skill in the art would not seek to modify Rajaiah to arrive at Applicants' claimed subject matter especially in view of the exemplary embodiments of Rajaiah disclosing the polybutene component as a liquid which can be enrobed within the chewing gum or confection outer shell.

The Examiners indicated that the presented arguments appeared to be persuasive, and that they would review the application upon submission of the written response. The Examiners also indicated that if the rejection was maintained and/or if a new ground of rejection was set forth, such rejection would address Applicants' arguments and set forth the type of showing that would be desired by the Examiners.

Arguments as presented during the interview are included in the remarks set forth herein.

Response to Art Based Rejections

The following art based rejections are set forth in the Office Action.

(a) Claims 1, 3-11, 13-16 and 20-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0072841 A1 to Rajaiah et al. (hereinafter "Rajaiah").

(b) Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rajaiah in view of Gibbs et al. (hereinafter "Gibbs"), International Journal of Food Sciences and Nutrition 1999.

(c) Claims 1, 3-11, 13-16 and 20-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajaiah in view of U.S. Patent No. 6,294,155 to Thomas et al. (hereinafter "Thomas").

(b) Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rajaiah and Thomas in view of Gibbs.

Applicant submits that the rejections based upon Rajaiah, either alone or in view of Gibbs, or Rajaiah in view of Thomas alone or further in view of Gibbs are without appropriate basis, and should be withdrawn at least for the reasons set forth below.

Applicant's independent claim 1 is directed to a solid, oral tooth whitening composition comprising more than 75% by weight of solid materials, said composition comprising:

- (a) a chewing gum or confectionary base;
- (b) chewing gum or confectionary additives; and

(c) a tooth whitening agent comprising calcium pyrophosphate present in an amount of between 3% and 8% by weight of the composition, excluding any coating compositions. As recognized in the rejections, Rajaiah does not teach such a composition. Instead, the rejections contended in the first Office Action that, despite the fact that one must "pick and choose" from different lists of components throughout the reference, that it would have been obvious in a self-evident manner to have selected, for the chewing gum/confectionary composition of Rajaiah, calcium pyrophosphate as well as sugar-free sweeteners, flavors, urea, vitamin C, and sodium bicarbonate, motivated by the unambiguous disclosure of each individually, and consistent with the basic principle of patent prosecution that a reference should be considered as expansively as is reasonable in determining the full scope of the contents within its four corners. Moreover, the rejections asserted that the adjustment of particular conventional working conditions of the composition of Rajaiah is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Presently, the rejections assert that the combination of known elements is obvious when it yields not more than one would expect from such an arrangement. The rejections further question whether the instant invention is more than the predictable use of prior art elements according to their established function.

In response, for at least the reasons set forth herein, Applicant again submits that the rejections do not establish a *prima facie* case of obviousness and do not address the unexpected showings presented by Applicant even if, for the sake of argument, a *prima facie* case of obviousness has been established.

Applicant submits that the rejections are without sufficient basis, because the rejections do not indicate how Rajaiah is being modified, but merely make ambiguous assertions. For

example, the rejections contended that the claimed subject matter is "obvious in a self-evident manner" in view of some asserted "basis principle of patent prosecution". However, the rejections did not indicate why one having ordinary skill in the art would have picked and chosen components disclosed in Rajaiah to arrive at Applicant's recited subject matter. This is especially the situation when there is no indication in the rejections what routine optimization would have been performed and/or why one having ordinary skill in the art would have manipulates the composition disclosed by Rajaiah to arrive at the claimed subject matter. This deficiency of the rejections has not been addressed previously, and is still not addressed in the present Office Action.

Rajaiah discloses in paragraph [0006] and [0007] that polybutene is recognized as a component of denture adhesives and as a gum base, and often employ higher molecular weight polybutene in order to achieve the desired result. Rajaiah discloses that in his invention lower molecular weight polybutene is incorporated into chewing gum and confection compositions to provide a protective coating on the teeth. Rajaiah discloses that the chewing gums and confections of his invention will release the lower molecular weight polybutene upon chewing or dissolution, thereby coating the teeth and hard surfaces of the oral cavity with sufficient substantivity to provide sustained release of the active. It is disclosed that the polybutene component of the chewing gum or confection thereby protects the hard surfaces from the buildup of plaque, bacteria and other debris, thereby inhibiting or preventing gingivitis, caries and staining, and that this coating also provides a slick, smooth feel to the hard surfaces of the oral cavity which consumers view as an indicator of clean teeth.

Rajaiah further discloses, in paragraph [0009], chewing gum formulations comprising two components; a polybutene component and a chewing gum component. **The polybutene**

component of the composition according to Rajaiah is a flowable liquid [0026], and thus not a "solid component". Thus, in order for the skilled person to arrive at the claimed subject matter starting from Rajaiah, in addition to "picking and choosing" the most suitable abrasive in the most preferred range, would also need to include the polybutene component of Rajaiah, which is an essential part of the composition disclosed by Rajaiah, in amounts that are not taught or suggested by Rajaiah, especially when Rajaiah discloses the importance of the liquid effect of his polybutene component.

Thus, to arrive at Applicant's claimed subject matter would require that the desired composition of Rajaiah, including the polybutene component, be essentially destroyed to arrive at the claimed subject matter. The rejections have not established any motivation and/or any reason why one having ordinary skill in the art would, in effect, attempt to modify what should be considered to be an essential component of the composition of Rajaiah to arrive at Applicant's claimed subject matter. While Applicant's claims do not exclude the presence of polybutene, one having ordinary skill in the art would not have modified Rajaiah to arrive at the composition recited in Applicant's independent claim 1, and further defined in the dependent claims with such a high concentration of solids.

The rejections contend that the composition of Rajaiah comprises more than 75% by weight of solid material insofar as it is chewing gum, and that Applicant has not defined solid material. However, one having ordinary skill in the art would understand the difference between solid and liquid, and the polybutene of Rajaiah is disclosed to be a liquid.

Moreover, the liquid polybutene of Rajaiah can be, as disclosed in paragraphs [0087] and [0088], homogeneously included in the chewing gum or confection composition, or can be enrobed within the chewing gum or confection outer shell composition by dipping, rolling or any

other coating means known in the art. Also, a center void into which the fill composition is injected is disclosed.

As previously indicated by Applicant, the rejections must establish that the prior art teaches or suggests, amongst the other features recited in Applicant's claims, a solid, oral tooth whitening composition comprising more than 75% by weight of solid materials. A mere assertion of "comprising solid materials" in the Final Office Action does not arrive at the claimed subject matter including more than 75% by weight of solid materials. However, the Office Action does not adequately address this issue.

Rajaiah discloses in paragraph [0024] that the compositions of his invention comprise polybutene of a lower molecular weight, from about 300 to about 3000, and is included from about 0.01% to about 99.9%, in another embodiment from about 1% to about 99%, and in yet another embodiment from about 50% to about 90%, by weight of the composition. However, this appears to be by weight of the polybutene component, as can be seen from the Table on page 10, including Examples 1-37. Moreover, when reference is made to the other ingredients in Rajaiah, such as the anti-calculus agent in paragraph [0032], reference is made to the polybutene component.

Rajaiah does not appear to disclose the mixing ratios of the polybutene component and the chewing gum or confection component, and the Examiner is requested to explicitly provide support if the Examiner determines that there is such disclosure in Rajaiah presented in an enabling manner.

Still further, there are additional deficiencies in Rajaiah. Rajaiah discloses in [0059] typical abrasive polishing materials as including "silica gels and precipitates; aluminas; water insoluble phosphates (including orthophosphates, polymetaphosphates, and pyrophosphates); and

mixtures thereof". In [0059], Rajaiah further discloses specific examples of abrasives as including dicalcium orthophosphate dihydrate, calcium pyrophosphate, tricalcium phosphate, calcium polymetaphosphate, insoluble sodium polymetaphosphate, hydrated alumina, beta calcium pyrophosphate, calcium carbonate, and resinous abrasive materials such as particulate condensation products of urea and formaldehyde and melamine urea formaldehyde. Mixtures of abrasives may also be used.

In [0059], Rajaiah further discloses that: "The abrasive in the chewing gum compositions is generally from about 1% to about 70%, in one embodiment from about 5% to about 50%, by weight of the chewing gum or confection component."

Rajaiah does not disclose a whitening effect of the abrasive and Rajaiah does not contain any teaching or suggestion as to the particular selection of calcium pyrophosphate among several other abrasives for any purpose, let alone as an abrasive having a superior whitening effect. Further, Rajaiah does not contain any teaching or suggestion as to the particular selection of the range of 3% to 8% calcium pyrophosphate on the basis of a proposed usable range of abrasive of 1-70%, or an embodiment from about 5% to about 50%, of the solid oral compositions.

Rajaiah does not disclose the whitening effect of the abrasive. Consequently, there is no teaching or suggestion to arrive at Applicant's claimed subject matter in Rajaiah.

Rajaiah does not disclose the specific features of the present invention and therefore does not disclose the solution of the present invention.

The rejections of record to do point to any disclosure of Rajaiah, or any other document, that would lead one having ordinary skill in the art to arrive at the recited tooth whitening agent comprising calcium pyrophosphate in an amount of 3 - 8%, as recited in Applicant's independent

claim 1. Rajaiah merely discloses the possibility of adding to a chewing gum calcium pyrophosphate as one abrasive among a myriad of other possible abrasives, with the abrasives being proposed to be applied in a range of 1-70% of the solid oral compositions.

Applicant further notes that calcium pyrophosphate, according to Rajaiah is placed as one among several abrasives [0059], though Rajaiah additionally teaches the possibility of adding whitening substances [0039] to solid oral compositions.

Calcium pyrophosphate is not mentioned among the preferred whitening agents mentioned in [0039] in Rajaiah. There is no teaching or suggestion in Rajaiah as to any particular suitability of calcium pyrophosphate as a whitening agent, and especially there is no teaching or suggestion in Rajaiah to the particular suitability of calcium pyrophosphate over other abrasives as a whitening agent.

Still further, while Rajaiah also discusses the use of pyrophosphates as potential anti-calculus agents in paragraph [0032], Rajaiah does not list calcium pyrophosphate as a possible candidate. Notwithstanding this, the paragraph states the anti-calculus agent may be present from about 0.001% to about 50%, by weight of the polybutene component (the polybutene component could be present in the composition between about 1% to 99.9%) and all of the examples clearly teach using much higher levels of anti-calculus agents (13, 15 and 25%) in the composition. Therefore, Rajaiah specifically teaches the skilled reader towards using a higher percentage of a pyrophosphate in a tooth whitening composition, rather than the range recited by Applicant.

The newly-instituted rejections try to overcome the deficiencies of Rajaiah by relying on Thomas for disclosing calcium pyrophosphate in a stain reduction test being used by definition

as 100. However, the rejection does not address Applicant's originally filed disclosure, such as at page 4, lines 11-23, of the unexpected effects of Applicant's claimed subject matter.

For example, it is disclosed that:

It has now surprisingly been demonstrated, using in vitro tests, that improved stain removal and stain inhibition effects of solid, oral compositions can be achieved using from 0.5 to 9% of calcium pyrophosphate as an abrasive agent, compared to the use of the often used abrasive, calcium carbonate. These effects are unexpected, seen in the light of the results presented in U.S. Pat. No. 3,590,120, in which the polishing effect of CaP_2O_7 was significantly poorer than that of CaCO_3 .

In addition to these results, it has also been surprisingly shown, using in vivo tests, that calcium pyrophosphate-containing chewing gum results in an improved removal of stain on tooth surfaces which do not normally come into contact with the gum while chewing, i.e. maxillary facial tooth surfaces, as well as on tooth surfaces on which stains build up rapidly and heavily and is the most difficult to remove, i.e. proximal tooth surfaces.

Moreover, the Examiner's attention is once again directed to the experiments disclosed in Applicant's specification. Prior art compositions comprising different concentrations of calcium pyrophosphate and calcium carbonate, respectively, have been tested, showing the superiority of a particular abrasive in a particular range for a particular purpose. Accordingly, the present application contains experimental data showing that calcium pyrophosphate is superior for whitening purposes to the commonly used calcium carbonate when formulated in chewing gum compositions (see e.g. table 1, page 16), and that calcium pyrophosphate is superior in inhibiting further discoloration of teeth (see e.g. table 2, page 18).

The experimental data in the originally filed application clearly shows that a lower amount of calcium pyrophosphate (4.5 to 6.5%) advantageously provides an improved tooth whitening effect, when compared to prior art tooth whitening agent calcium carbonate

As discussed with the Examiners during the above-noted interviews, **the rejections have never addressed these showings except to make the general assertion that the showings are not persuasive. The rejections improperly do not provide any explanation as to what is considered to be any deficiency in the showings in the originally filed application. Accordingly, the Examiner is requested to provide a complete response to Applicant's arguments relating to the unexpected showings in the originally filed application.**

Therefore, for at least for the reasons set forth above, the rejections do not establish a *prima facie* case of obviousness. Moreover, the Office Action does not address the unexpected showings demonstrated in Applicant's originally filed application. Thus, for at least the reasons set forth above, the composition recited in Applicant's independent claim 1 is not taught or suggest by Rajaiah or Rajaiah in view of Thomas.

Moreover, the dependent claims further patentably define the claimed subject matter, and are patentable for the features set forth the independent claim as well as for the features recited therein.

Claim 3 further patentably recites that the gum base constitutes from 10% to 99% by weight of the composition.

Claim 4 further patentably recites that the gum base comprises at least one of the following; natural or synthetic elastomeric compounds, natural or synthetic resin compounds, fillers, softening compounds, antioxidants and colorants.

Claim 5 further patentably recites that the composition is formulated as a confectionary composition in which said confectionary base constitutes from 0% to 99% by weight of the composition.

Claim 6 further patentably recites that the chewing gum or confectionary additives

comprise at least one of the following ingredients: sweeteners, high intensity sweeteners, taste enhancers, flavoring agents, and coloring agents.

Claim 7 further patentably recites that the composition is essentially sugar-free.

Claim 8 further patentably recites that the composition comprises at least one additional tooth whitening agent.

Claim 9 further patentably recites that the at least one additional tooth whitening agent is present in between 0.01% and 10.0% by weight of the composition, excluding any coating.

Claim 10 further patentably recites that the at least one additional tooth whitening agent comprises a bicarbonate salt.

Claim 11 further patentably recites that the at least one additional tooth whitening agent comprises sodium bicarbonate, said agent being present in between 0.3% and 0.4% by weight of the composition, excluding any coating.

Claim 12 further patentably recites that the at least one of said additives and said tooth whitening agent is encapsulated.

Claim 13 further patentably recites that the composition further comprise at least one of the following: oral hygiene promoting agents, anti-calculus agents, anti-microbial agents, anti-inflammatory agents, desensitizing agents, therapeutically active agents, and remineralizing agents.

Claim 14 further patentably recites that the composition further comprises a supplement.

Claim 15 further patentably recites that the supplement comprises vitamin C.

Claim 16 further patentably recites that the oral hygiene promoting agent comprises urea, said urea being present in between 0.15% and 25% by weight.

Claim 23 further patentably recites that the calcium pyrophosphate is present in an

amount of between 4.5% and 7.5 % by weight of the composition, excluding any coating compositions.

Claim 24 further patentably recites that the calcium pyrophosphate is present in an amount of between 5.5% and 7 % by weight of the composition, excluding any coating compositions.

Claim 25 further patentably recites that the composition is formulated as a chewing gum composition wherein which said gum base constitutes from 15% to 80% by weight of the composition.

Claim 26 further patentably recites that the composition is formulated as a chewing gum composition wherein said gum base constitutes 25% to 60 % by weight of the composition.

Claim 27 further patentably recites that the at least one additional tooth whitening agent is present in between 0.1 and 2.0% by weight of the composition, excluding any coating.

Claim 28 further patentably recites that the at least one additional tooth whitening agent is present in between 0.25% and 1.0% by weight of the composition, excluding any coating.

Claim 29 further patentably recites that the oral hygiene promoting agent comprises urea, said urea being present in between 0.4% and 10% by weight.

Claim 30 further patentably recites that the oral hygiene promoting agent comprises urea, said urea being present in between 0.8% and 5% by weight.

Claim 31 further patentably recites the oral hygiene promoting agent comprises urea, said urea being present in between 1.5 % and 2.5% by weight.

Claim 20 patentably recites a method of whitening tooth surfaces by consuming a solid, oral tooth whitening composition according to claim 1, which method is not taught or suggested in Rajaiah.

Claim 21 patentably recites a method of whitening tooth surfaces by consuming a solid, oral tooth whitening composition according to claim 1, said tooth surfaces being discolored after use of tobacco-related products, which method is not taught or suggested in Rajaiah.

Claim 22 patentably recites a method of whitening tooth surfaces by consuming a solid, oral tooth whitening composition according to claim 1, said tooth surfaces being discolored after use of coffee-related products, which method is not taught or suggested in Rajaiah.

Gibbs is utilized in the rejection of claim 12 solely for assertions that it would have been obvious to encapsulate to arrive at the subject matter recited in claim 12. However, whether or not encapsulation would have been obvious in view of Gibbs, for at least the reasons set forth above, Applicant's claimed subject matter would not be at hand.

Accordingly, the rejections of record should be withdrawn.

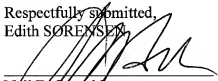
CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
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